K082441

510(k) Summary

NOV 21 2008

510(k) Type: Traditional
Submission Date: 08.22.2008

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Predicate device name and 510(k) number: Nordic Image Control and Evaluation (nordicICE) Software, K063539

Trade/Proprietary Name: nordicICE Software
Device Common Name: PACS

Classification Regulation: 892.2050

Class: II
Panel: Radiology
Product Code: LLZ

Device Description

nordicICE (nICE) – Nordic Image Control and Evaluation software - is a medical viewing, analysis, and processing package developed with a view to ease of use and high performance on a standard Windows platform. The software provides a wide range of basic image processing and manipulation functions, in addition to comprehensive functionality for dynamic image analysis and processing/display of functional MRI (fMRI) data. The main user of the program will be imaging professionals who need to visualize and analyze images taken primarily from a MRI system.

Intended Use

nordicICE is an image processing software package to be used by trained professionals including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" PC workstation and can be used to perform image viewing, processing and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities.

nordicICE provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including blood oxygen level dependent (BOLD) fMRI, diffusion weighted MRI (DWI) / fiber tracking and dynamic analysis.

BOLD fMRI: BOLD analysis is used to highlight small magnetic susceptibility changes in the human brain in areas with altered blood-flow resulting from neuronal activity.

DWI/Fiber Tracking: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilize the directional dependency of the diffusion to display the white matter structure in the brain.

Dynamic Analysis: Dynamic analysis is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time where such techniques are useful or necessary.

Substantial Equivalence

nordicICE has been verified and validated according to NIL's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by nordicICE was found to be substantially equivalent with the predicate device Nordic Image Control and Evaluation (nordicICE) Software (K063539).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2008

Ms. Stian Scisly Sagevik
Quality Manager
NordicimagingLab AS
Møllendalsveien 65C
N-5009 Bergen
NORWAY

Re: K082441
Trade/Device Name: Nordic Image Control and Evaluation (nordicICE) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 24, 2008
Received: October 14, 2008

Dear Ms. Sagevik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082441

Device Name: Nordic Image Control and Evaluation (nordicICE) Software

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082441